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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,677	02/05/2001	Jan Otto Solem	JM-050 CIP	3473

7590 07/12/2006
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EXAMINER
ISABELLA, DAVID J

ART UNIT 3738	PAPER NUMBER
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DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL.

Examiner

DAVID J. ISABELLA

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 22, 25-27, 30, 32-40, 74 and 86-89 is/are pending in the application.
- 4a) Of the above claim(s) 25-27, 32-36 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22, 30, 37-40 and 86-88 is/are allowed.
- 6) ☒ Claim(s) 14, 17 and 89 is/are rejected.
- 7) ☐ Claim(s) 15, 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Request for Continued Examination

This amendment is submitted in response to the Office action mailed December 27, 2005. Claims 22, 25-27, 30, 37, 38, 40, 74 and 86 have been amended. Claims 25-27, 32-36, 74 remain withdrawn. Accordingly, claims 14-17, 22, 30, 37-40 and 86-89 are currently pending. April 6, 2006, a personal interview was conducted with the Examiner.

Response to Amendment

The amendment filed 4/27/2006 has been entered. Claims 75-85 have been canceled, and new claims 86-89 have been added. The claims being considered for further examination on the merits are claims 14-17, 22, 30, 37-40 and 86-89.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

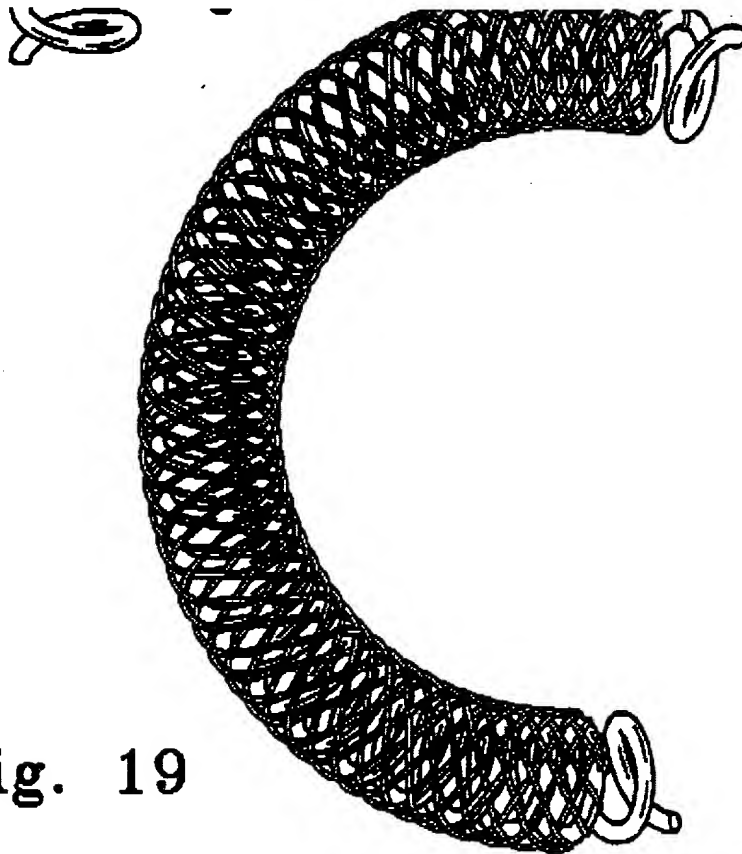
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 17 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Phelps et al [5382259].

Phelps et al discloses a medical comprising an elongate body adapted to be fixed to a vessel, the elongate body extending between a proximal end and a distal end, and that is adjustable from a first configuration having a first shape such that the

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elongate body is adapted to be delivered at least in part into the vessel to a second configuration having a second shape such that the elongate body is capable to exert a force from within the vessel onto the tissue that would remodel the shape of the extravascular tissue. See figure 19.

**Fig. 19*****Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran (USPN 5,817,126, as cited in applicant's IDS) in view of Orth et al. (USPN 5,591,197, as cited in last office action).

Imran discloses a medical device and medical system for remodeling an extravascular tissue structure adjacent to a vessel/body space in a patient and an apparatus with all the elements of claims 22, 38 and 40, but is silent to the elongate body being adapted to be fixed to the vessel/body space and to exert a force from within the coronary sinus onto the mitral valve annulus in order to remodel the mitral valve annulus. See Figure 1 for a medical device (10) comprising an elongate body (11) extending between a proximal end (24) and a distal end (44), and that is adjustable from a first configuration having a first shape such that the elongate body is adapted to be delivered at least in part into the vessel/body space to a second configuration having a second shape (column 1, lines 18-24). See column 3, lines 26-43 for the dimensions of the elongate body (11) being within ranges that would allow for it to be inserted into and positioned in the first configuration at least in part within a coronary sinus. See Figure 1 for the distal end (44) of the elongate body (11) being spaced distally from the proximal end (24) of the elongate body (11) in the first and second configurations. See columns 6-7, lines 58-3 for a deployment system cooperating with the elongate body (11) and being adapted to and capable of at least in part delivering the elongate body (11) in the first configuration to the coronary sinus. See Figure 1 and columns 3-4, lines 63-1 for

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the elongate body (11) having two first segments (20, 40) and a second segment (60) disposed between the first segments (20, 40). See column 6, lines 35-37 for the second segment (60) being capable of decreasing its axial length to draw one of the first segments towards the other first segment.

Orth et al. teaches a stent (10) that forms barbs upon expansion for contacting and penetrating the vessel wall in order to anchor and affix the stent thereto. See column 1, lines 8-9, column 3, lines 33-35 and column 7, lines 45-47. It would have been obvious of one of ordinary skill in the art to look to the teachings of Orth et al. to modify the elongate body (11) of Imran by having the two first segments (20, 40) be barb forming stents in order for the barbs to contact and penetrate the vessel wall. This will anchor and affix the stent to the vessel wall and prevent migration of the stent. The elongate body is adapted to adjust to the second configuration after it is fixed to the coronary sinus in the following manner: when the first segments (20, 40) are expanded and affixed to the coronary sinus wall, subsequent expansion of the second segment (60) will reduce a longitudinal length of a portion of the coronary sinus by drawing one of the first segments attached to a first portion of the coronary sinus towards the other first segment attached to a second portion of the coronary sinus. See column 5, lines 62-65. This will cause the elongate body (11), which is fixed to the coronary sinus, to exert a force from within the coronary sinus onto the mitral valve annulus and remodel the mitral valve annulus without fully encircling the mitral valve annulus (claim 86).

Allowable Subject Matter

Claims 22, 30, 37-40 and 86-88 are allowed.

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 4/27/2006 have been fully considered but they are not persuasive.

With respect to claims 14 and 89, although Phelps, et al does not disclose use of the stent within the coronary sinus, the stent is structurally capable of being used therein.

In response to applicant's argument that neither Imran nor Orth teach or suggest that the stent is adapted "after it is fixed to the coronary sinus" to remodel a mitral valve annulus adjacent to the coronary sinus, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Imran discloses in column 3, lines 26-43 the dimensions of the stent as being within ranges that would allow for it to be inserted into and positioned in the first configuration at least in part within a coronary sinus. Therefore, although Imran does not disclose use of the stent within the coronary sinus, the stent is structurally capable of being used therein. Imran also discloses in column 6, lines 22-39 that the three segments (first

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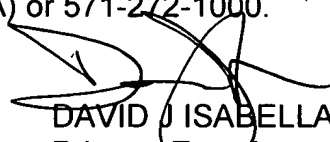
segments 20, 40 and second segment 60) of the stent are separately made and then assembled together. The segments are assembled in such a manner that they are structurally capable of independent expansion. Applicant has not provided evidence to prove otherwise. While Imran does disclose the deployment of the full stent in one step, the stent is structurally capable of being deployed in other fashions, specifically expansion of first segments (20, 40) followed by subsequent expansion of second segment (60). It is not required for product claims 22, 38 and 40 that the prior art disclose the method of expansion of the stent being in this specific fashion. Because the stent of Imran is *capable of* being expanded in this fashion, the limitation is met. When the stent of Imran is modified according to the teachings of Orth and expanded in the specified fashion, the change in length of the stent will occur *after* first segments (20, 40) are fixed in place by the barbs and during expansion of the second segment (60).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
6/28/2006